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APPLICATION N	Ю.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,837		09/26/2003	Menachem Kraus	U014834-5	. 1334
140	7590	03/30/2004		EXAMINER	
LADAS 26 WEST			KIM, SUN U		
NEW YO			•	ART UNIT	PAPER NUMBER
				1723	
				DATE MAIL ED: 03/30/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

·	Application No.	Applicant(s)				
	10/672,837	KRAUS ET AL.				
Office Action Summary	Examiner	Art Unit				
	John Kim	1723				
The MAILING DATE of this communication apports. Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 26 Se	ptember 2003.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex	x <i>parte Quayle</i> , 1935 C.D. 11, 45	3 O.G. 213.				
Disposition of Claims						
4) Claim(s) 2-21 is/are pending in the application.						
4a) Of the above claim(s) is/are withdraw	n from consideration.	•				
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>2-21</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner						
10) ☐ The drawing(s) filed on <u>26 September 2003</u> is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Exa						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign p	priority under 35 U.S.C. & 119(a).	-(d) or (f)				
a)⊠ All b)□ Some * c)□ None of:	5.101kg and 00 0.0.0. 3 1 10(a)	(4) 51 (1).				
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No. 09/963,427.						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
	·					
Attachment(c)						
Attachment(s) Notice of References Cited (PTO-892)	/) \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	DTO 412)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) 🔲 Interview Summary (Paper No(s)/Mail Dat					
 Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/26/03. 	5) Notice of Informal Pa	tent Application (PTO-152)				
Patent and Trademark Office	6)					

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- 1. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. For instance, a recitation of "This application is a division of application no. 09/693,427 filed 10/23/00 issued as U.S. Patent No. 6,629,613." should be included in the first sentence of the specification.
- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 2-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,476,587 (hereinafter referred to as Kuroki et al '587). Kuroki et al '587 teach a method of using a leukocyte filter having a non-woven prefilter and at least one layer of non-cellulosic membrane filter layer having an average pore size ranging from 1 to 5 microns wherein the percentage of the pore volume constituted by pores having specific range of pore cross section diameter are adjusted depending on the use of the leukocyte filter such as leukocyte-separating filter, filter for separating leukocytes and platelets, leukocyte remover and leukocyte/platelet remover for removing leukocytes from blood components such as red blood cells or platelets and/or from whole blood wherein Examples 7-9 in Table 2 shows most frequent pore diameter from 4 microns to 5 microns; furthermore, Kuroki et al '587 teaches that the number of porous

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sheets laminated may appropriately determined by considering the removal rate, filtration time and likelihood of clogging, etc. (see col. 4, line 4 – col. 15, line 26; particularly col. 2, lines 13-19; col. 5, line 60 – col. 6, line 2; col. 6, lines 42-48; col. 8, line 27 – col. 9, line 29; col. 10, line 11 –col. 11, line 5; col. 11, lines 12-58; col. 12, line 37 – col. 15, line 7). Claims 2-21 essentially differ from the method and apparatus of Kuroki et al '587 in reciting claimed limitation of pore surface area/membrane volume ratio or total pore volume of pores having claimed diameters or pore size distribution, etc. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the percentage of the pore volume constituted by pores having specific range of pore cross section diameter in the leukocyte filter of Kuroki et al '587 to arrive at the claimed invention for its use as a leukocyte filter for a specific purpose.

Claims 2-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,478,470 (hereinafter referred to as Fukuda et al '470). Fukuda et al '470 teach a method of using a leukocyte filter having a prefilter layer and at least one layer of non-cellulosic membrane filter layer having an average pore diameter of 1 to 25 microns and a total pore volume of 0.4 to 0.95 ml/ml of the porous element wherein the sum of respective pore volumes of pores of the porous element which have a pore diameter of 1 to 30 microns is 90% or more (see abstract) and the porous element has a total pore surface area of 0.5 to 5.7 square meter per ml with the proviso that the sum of respective pore surface areas of pores of the porous element which have a pore diameter of 2 to 30 microns is 50% or more based on the total surface area (see col. 5, lines 47-51) and the sum of respective pore volumes of pores of the porous element which have a pore diameter of less than 2 microns is 8% or less based on the total pore volume (see col. 5, lines 56-59) and the percentage of the pore volume constituted by pores having specific range of pore

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cross section diameter are adjusted depending on the use of the leukocyte filter for removing leukocytes from different leukocyte containing suspensions such as a leukocyte-containing red cell product and/or a leukocyte-containing platelet product wherein Examples 1-8 shows average pore diameter from 7.4 microns to 9.2 microns in Table 1-2 and Example 4 shows that the pore volume of pores having diameter exceeding 10 microns is 5% of the total pore volume in Table 2 (see col. 4, line 12 – col. 32, line 3). Claims 2-21 essentially differ from the method and apparatus of Kuroki et al '587 in reciting claimed limitation of pore surface area/membrane volume ratio or total pore volume of pores having claimed diameters or pore size distribution, etc. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the percentage of the pore volume constituted by pores having specific range of pore cross section diameter in the leukocyte filter of Fukuda et al '470 to arrive at the claimed invention for its use as a leukocyte filter for filtering specific leukocyte-containing suspension.

- 5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,168,718 and 6,629,613 and US 2003/0234226 and US 2003/0208181 teach leukocyte filters.
- 6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 7:00 AM 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for official response is (703) 872-9306.

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When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

John Kim
Primary Examiner
Art Unit 1723

J. Kim March 22, 2004